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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,813	04/20/2001	Robert Henry	54195-5001	3042

7590 08/24/2004

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,813	HENRY ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-30 and 32-47* is/are pending in the application.

4a) Of the above claim(s) *32-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-30 and 43-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 5/17/2004 has been entered.

Claims 22-30 and 32-47 are pending.

Claims 32-42 are withdrawn from consideration for being drawn to non-elected inventions.

Claims 43-47 are newly added.

2. Claims 22-30 and 43-47 are examined in the present office action.

3. Rejections and objections not set forth below are withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Oath/Declaration

5. The Office acknowledges Applicants' intention to submit a new Oath listing priority to PCT/AU99/00897, and not claiming priority to PCT/US0024244.

The Office acknowledges the Utility Patent Application Transmittal form which claims a continuation of PCT/AU99/00897 filed October 18, 1999 and Provisional Patent Application No. PP6646 filed October 22, 1998.

New Matter

6. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/13/2004. Applicant's arguments filed 5/17/2004 have been fully considered but they are not persuasive.

Applicants contend that claim 25 does not contain new matter. Applicants contend that the specification incorporates by reference Weining and Langridge (1991, Theor. Appl. Genet. 82:209) in order to illustrate one aspect of the state of the art of DNA isolation at the time of filing of the present application, namely, the use of cesium chloride fractionation to isolate high-molecular weight genomic DNA from a plant (page 8, 1st paragraph). Applicants contend that Weining and Langridge describe in detail a method of DNA isolation using cesium chloride fractionation (page 8, 2nd paragraph).

The Office contends that Weining and Langridge do not teach in detail cesium chloride fractionation, but rather state "The DNA was further purified via CsCl equilibrium centrifugation" and then reference another reference (page 210, right column, end of 1st full paragraph).

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Scope of Enablement

7. Claims 22-30 and 43-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of transferring DNA directly isolated from *Zizania palustris* and a plasmid encoding a selectable marker into *Oryza sativa* cultivar Jarrah using microprojectile bombardment and then selecting transformed *Oryza* plants and using Amplified Fragment Length Polymorphism (AFLP) to characterize the range of introgression of *Zizania* DNA into transformed *Oryza*, wherein the range of introgression was from 1.7% to 6.7% meaning that 1.7% to 6.7% of *Z. palustris* specific AFLP markers were present in the individuals tested, does not reasonably provide enablement for a method of transferring a gene into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant and selecting at least one transgenic plant wherein said transgenic plant has a genome comprising a nucleic acid that corresponds to 0.01% to 10% of a nucleic acid genome of said donor plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the

invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method of transferring plant DNA into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant and selecting at least one transgenic plant wherein said transgenic plant has a genome comprising a nucleic acid that corresponds to 0.01% to 10%, 1% to 10%, or 1.7% to 6.7% of a nucleic acid genome of said donor plant, wherein the selected plant comprises a plurality of genetic markers wherein said genetic markers are Amplification Fragment Length Polypmorphism (AFLP), wherein said isolated DNA is genomic DNA or wherein said DNA is high molecular weight DNA obtainable by cesium chloride fractionation or wherein a selection marker gene is present in a selection construct or wherein both donor and recipient are cereal plants and wherein said donor plant and said recipient plant are members of different species or different genera or wherein both donor and recipient are cereal plants and the donor plant is a species of *Zizania palustris*. The claims are also drawn to transforming a species of *Oryza sativa*.

Applicants disclose transforming *Oryza sativa* cultivar Jarrah with DNA isolated from *Zizania palustris* and the plasmid pGL2 encoding the hygromycin-resistance (*hmr*) gene using microprojectile bombardment. The genomic DNA was not inserted into a plasmid vector but rather was directly immobilized along with the plasmid encoding hygromycin phosphotransferase onto gold particles (pages 13-14, lines 5-33, and lines 1-16; page 16, lines 23-32). Applicants selected transformed callus on medium comprising Hygromcin B and then regenerating transformed plants. Applicants analyzed the extent

of genome transfer into transformed *O. sativa* plants using AFLP analysis and report that the range of introgression was from 1.7% to 6.7% meaning that 1.7% to 6.7% of *Z. palustris* specific AFLP markers were present in the 7 individuals tested (page 17, lines 13-22).

Applicants have only taught the introduction of *Zizania* DNA into *Oryza* and then the analyzsis of the introgressed DNA using AFLP analysis. Applicants have not taught the introduction of any directly isolated plant DNA into any plant species and then the analysis of the introgressed DNA using AFLP. Applicants have not disclosed the primer sequence or PCR conditions that must be used to analyze all transformed plants. There are thousands of different primer pair combinations that must be analyzed to determine which one best identifies the DNA of interest and that shows a polymorphism with the DNA of the recipient plant. (The number of primer pairs is calculated by multiplying all the different possible 3', one, two or three base pair overhangs times the different restriction/linker primers.) In addition, Applicants have not taught how one skilled in the art would calculate the percentage of donor plant DNA in a recipient plant. Again, one skilled in the art would have to establish genetic markers that correlate with specific segments of DNA from the donor plant so as to be able to evaluate the percentage of donor plant DNA in the recipient. Applicants have not disclosed any information that one skilled in the art can to enable the analysis without undue trial and error experimentation.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through all the different possible primer pairs which includes optimizing the PCR conditions so that a polymorphism is

detected between the donor plant and recipient plant that can be discerned on a gel electrophoresis and then using this protocol to evaluate the percentage of DNA from the donor plant that has been introgressed into a recipient plant.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

103 Obviousness

8. Claims 22-25, 27, 28, and 30 remain rejected and claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turbin et al (1975, Mutation Research 27:59-68) in view of Christou (1997 Plant Molecular Biology 35:197-203) and further in view of Eshed et al (1992, Theor. Appli. Genet. 83:1027-1034) and Keim et al (1997, Crop Sci. 37:537-543).

The claims are drawn to a method of transferring plant DNA into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant and selecting at least one transgenic plant wherein said transgenic plant has a genome comprising a nucleic acid that corresponds to 0.01% to 10%, 1% to 10%, or 1.7% to 6.7% of a nucleic acid genome of said donor plant, wherein the selected plant comprises a plurality of genetic markers wherein said genetic markers are amplification fragment length polypmorphism (AFLP), wherein said isolated DNA is genomic DNA or wherein said DNA is high molecular weight DNA obtainable

by cesium chloride fractionation or wherein a selection marker gene is present in a selection construct or wherein both donor and recipient are cereal plants. The claims are also drawn to transforming a species of *Oryza sativa*.

Turbin et al teach a method of transforming a barley plant with directly isolated genomic DNA isolated from another species of barley (page 61 and 62, see "Extraction of DNA from the endospermal material" and "Extraction of DNA from leaves"), which is a cereal plant. It would have been an inherent process of the Turbin et al method to propagate transformed plants (page 63, see "Examination of the pollen of plants grown from the injected grains"). The office interprets said DNA to be high molecular weight DNA because both processes of isolating DNA produce long molecules of DNA which would be obtainable by cesium chloride fractionation.

Turbin et al do not teach transforming a plant using microprojectile bombardment wherein the plant is a species of *Oryza sativa*, incorporating a selection marker gene in a construct, selecting a plant comprising 0.01% to 10%, 1% to 10%, or 1.7% to 6.7% of a nucleic acid genome of said donor plant and wherein the selected plant comprises a plurality of genetic markers wherein said genetic markers are amplification fragment length polypmorphism (AFLP).

Christou teaches a method of transforming *Oryza sativa*, cultivars Gulfmont, IR72 and Koshihikari using microprojectile bombardment and transforming a plant with a selection marker (the bar gene) gene that is present in a selection construct (page 201, sentence bridging left and right columns).

Eshed et al teach tomato introgression lines in which *Lycopersicon esculentum* has been introgressed with DNA from *L. pennellii* wherein the introgressed DNA

contains various percentages of *L. pennellii* DNA, up to 50% and Eshed et al use molecular markers to ascertain the identity of the introgressed DNA (page 1028, Material and methods section and page 1028, right column, last paragraph and page 1029, right column).

Keim et al teach the use of AFLP markers (page 538, Material and methods).

Given the recognition of those of ordinary skill in the art of the value of transforming rice for the purpose of moving rice improvement programs forward as taught by Christou (page 197, right column, 3rd and 4th sentence from the bottom), it would have been within the scope of one of ordinary skill in the art to modify the method of Turbin et al and to use the microprojectile bombardment method as taught by Christou. One of ordinary skill in the art would have been motivated to combine the method of Turbin et al with the microprojectile bombardment method of Christou because of the success of Eshed et al at improving a crop plant (tomato) by introducing DNA from a related species of tomato for the purpose of improving genetic diversity which facilitates improvements in breeding programs. One of ordinary skill in the art would have used the directly isolated DNA method as taught by Turbin et al and to combine it with the method of DNA transfer as taught by Christou. Given the teachings of Eshed et al that show that the introduction of large segments of DNA from a different species of plant is possible and improves the characteristics of the recipient plant, and the introduced DNA can be characterized using molecular markers, which include using the AFLP markers as taught by Keim et al, adds to the motivation for transforming rice using the teaching of both Turbin et al combined with Christou. It would have been optimization of process parameters to produce a plant or rice plant wherein the introduced DNA corresponds to

0.01% to 10%, 1% to 10%, or 1.7% to 6.7% of a nucleic acid genome of said donor plant. Additional motivation is taught by Christou who states that microprojectile bombarment is "the best method for achieving truly genotype-independent transformation" (page 198, right column, 1st paragraph).

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicant's arguments filed 5/17/2004 have been fully considered but they are not persuasive.

Applicants contend that neither Turbin nor Christou teach or suggest all the claim limitations of amended claim 22. Neither reference teach or suggest the step of selecting recipient transgenic plants that have an equivalent of 0.01% to 10% of a donor plant genome incorporated therein (page 10, 3rd paragraph).

The Office contends that Eshed et al teach introgressing DNA from one species of tomato into another and that the introgressed lines contain up to 50% DNA from the donor plant and selecting a plant with 0.01% to 10% DNA from the donor plant is simply a design choice. Eshed et al also teach the use of genetic markers to identify donor DNA in the recipient plant.

Applicants contend that Turbin does not teach or suggest large scale introgression of donor genes. Applicants contend that the Christou reference does not disclose transforming with multiple genes except where they teach transforming with three selection marker genes. Applicants contend that Christou therefore does not teach or

suggest transfer of donor plant nucleic acids in the absence of a vector, wherein 0.01% - 10% of the donor plant genome is transferred to the transgenic plant (page 10, 4th and 5th paragraphs).

As discussed above, Eshed et al teach large scale introgression. In regards to donor DNA in the absence of a vector, Applicants teach that the directly isolated DNA may be ligated into a vector (See page 8, 3rd paragraph). Applicants' arguments are not commensurate in scope with the claimed invention and although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants contend that Turbin and Christou teach away from the present invention because the Turbin and Christou references, when taken together, suggest that integration of multiple genes into the genome of a recipient plant could be successfully achieved by delivery of donor DNA contained within a vector, but not absent the use of a vector delivery vehicle (page 11, top paragraph).

The Office contends that Applicant is arguing limitations not specified in the claims, as discussed above.

Applicants contend that there would not have been any motivation to combine the Turbin and Christou references. Applicants contend that the references teach integration of multiple genes into a recipient plant could be successful only using a vector (page 11, middle paragraph).

The Office contends that the combined references do not teach that donor DNA must be contained within a vector. In fact, Turbin did not use a vector and transformation was successful.

Applicants contend there was simply no reasonable expectation of success, that the combination of these references could arrive at the invention recited in claims 22-25, 27, 28, and 30 given conventional wisdom that plant transformation by microprojectile bombardment was best achieved using one or a few genes inserted into one or more plasmid vectors (page 11, last paragraph).

The Office contends that "conventional wisdom" for one person is not the same for another person. The Office invites Applicants to submit documentation attesting to Applicants' "conventional wisdom".

9. Claims 26 and 29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Turbin et al (1975, Mutation Research 27:59-68) in view of Christou (1997 Plant Molecular Biology 35:197-203) and further in view of Eshed et al (1992, Theor. Appli. Genet. 83:1027-1034) and Keim et al (1997, Crop Sci. 37:537-543) as applied to claims 22-25, 27, 28, 30 and 43-47 above, and further in view of Applicants' own admitted statement of the prior art (page 18, lines 17-18, Xiao et al 1996. Nature 384:223-) and Weining et al (1991 Theor. Appl. Genet. 82:209-216).

The claims are drawn to a method of transferring plant DNA into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant and selecting at least one transgenic plant wherein said transgenic plant has a genome comprising a nucleic acid that corresponds to 0.01% to 10%, 1% to 10%, or 1.7% to 6.7% of a nucleic acid genome of said donor plant, wherein the selected plant comprises a plurality of genetic markers wherein said genetic markers are amplification fragment length polypmorphism (AFLP), wherein said isolated

DNA is genomic DNA or wherein said DNA is high molecular weight DNA obtainable by cesium chloride fractionation or wherein a selection marker gene is present in a selection construct or wherein both donor and recipient are cereal plants and wherein said donor plant and said recipient plant are members of different species or different genera or wherein both donor and recipient are cereal plants and the donor plant is a species of *Zizania palustris*. The claims are also drawn to transforming a species of *Oryza sativa*.

Turbin et al in view of Christou, Eshed et al and Keim have been discussed above.

Turbin et al in view of Christou, Eshed et al and Keim do not teach a donor plant and recipient plant from different genera nor where the donor plant is of the species *Zizania palustris*.

Applicants' admitted statement of the prior art teach wild members of *Oryzae* have been shown to be important sources of genes for improvement of yield wherein *Zizania palustris* is a wild rice species but is classified as a different genus compared to *Oryzae*.

Weining et al teach isolation of DNA from grasses and cereal plants.

Given the recognition of those of ordinary skill in the art of the value of producing a rice plant transformed with high molecular DNA isolated from another species of rice plant and transformed by microprojectile bombardment as taught by Turbin et al in view of Christou, Eshed et al and Keim (see above), it would have been obvious to use the method of Turbin et al in view of Christou, Eshed et al and Keim and to modify this method taught by Applicants' own admitted statement of the prior art by isolating DNA from the wild rice species, *Zizania palustris* using the method as taught by Weining et al.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicant's arguments filed 5/17/2004 have been fully considered but they are not persuasive.

Applicants contend that Turbin et al does not teach the claimed method as stated in claims 26 and 29 for the reasons given above (page 12, 5th paragraph).

The Office contends that the above response overcomes Applicants arguments.

Applicants contend that Xiao and Weining do not teach or suggest the transfer of donor plant nucleic acids in the absence of a vector wherein 0.01%-10% of the donor plant genome is transferred to a recipient plant of a different genus, nor do they teach selection of plants with said nucleic acids.

The Office contends that Eshed et al teach introgressing DNA from a donor plant into a recipient plant and identifying said DNA using molecular markers, as discussed above. The success of Eshed et al, and the teachings of Turbin et al for isolating high molecular weight DNA to be used to transform a plant, taken with the method of transforming a plant of Christou, makes obvious the broadly claimed method.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
August 6, 2004

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